SECTION 1: Identification

1.1. Identification
Product name: Ropivacaine hydrochloride injection
Other means of identification:
- NDC 55150-195-20 (40 mg/20mL Single Dose Vials)
- NDC 55150-196-99 (200 mg/100 mL Single Dose Infusion Bottles)
- NDC 55150-197-20 (100 mg/20 mL Single Dose Vials)
- NDC 55150-198-30 (150 mg/30 mL Single Dose Vials)
- NDC 55150-199-20 (150 mg/20 mL Single Dose Vials)
- NDC 55150-200-10 (100 mg/10 mL Single Dose Vials)
- NDC 55150-201-20 (200 mg/20 mL Single Dose Vials)

1.2. Relevant identified uses of the substance or mixture and uses advised against
Use of the substance/mixture: Pharmaceutical

1.3. Details of the supplier of the safety data sheet
AuroMedics
6 Wheelling Road
Dayton, NJ 08810
T 609-642-1136

1.4. Emergency telephone number
Emergency number: 888-238-7880, option 2

SECTION 2: Hazard(s) identification

2.1. Classification of the substance or mixture
GHS-US classification
- Eye Irrit. 2A H319
- STOT RE 2 H373

Full text of classification categories and H statements: see section 16

2.2. Label elements
GHS-US labeling
Hazard pictograms (GHS-US):

Signal word (GHS-US): Warning
Hazard statements (GHS-US):
- H319 - Causes serious eye irritation
- H373 - May cause damage to organs through prolonged or repeated exposure

Precautionary statements (GHS-US):
- P260 - Do not breathe dust/fume/gas/mist/vapors/spray
- P264 - Wash thoroughly after handling
- P280 - Wear protective gloves/protective clothing/eye protection/face protection
- P305+P351+P338 - If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing
- P314 - Get medical advice/attention if you feel unwell
- P337+P313 - If eye irritation persists: Get medical advice/attention
- P501 - Dispose of contents/container in accordance with local/regional/national/international regulations.

2.3. Other hazards
No additional information available

2.4. Unknown acute toxicity (GHS US)
Not applicable
Ropivacaine hydrochloride injection
Safety Data Sheet

SECTION 3: Composition/information on ingredients

3.1. Substance
Not applicable

3.2. Mixture

<table>
<thead>
<tr>
<th>Name</th>
<th>Product identifier</th>
<th>%</th>
<th>GHS-US classification</th>
</tr>
</thead>
<tbody>
<tr>
<td>(2S)-N-(2,6-Dimethylphenyl)-1-propylpiperidine-2-carboxamide</td>
<td>(CAS No) 132112-35-7</td>
<td>0.2 - 1</td>
<td>Eye Dam. 1, H318</td>
</tr>
</tbody>
</table>

Full text of classification categories and H statements: see section 16

SECTION 4: First aid measures

4.1. Description of first aid measures

First-aid measures after inhalation: Remove from source of exposure. If signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.

First-aid measures after skin contact: Remove from source of exposure. Flush with copious amounts of water. If irritation persists or signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.

First-aid measures after eye contact: Remove from source of exposure. Flush with copious amounts of water. If irritation persists or signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.

First-aid measures after ingestion: Remove from source of exposure. If signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.

4.2. Most important symptoms and effects, both acute and delayed

Symptoms/injuries after inhalation: None anticipated from normal handling of this product. However, inadvertent contact of this product with the respiratory system may produce irritation and numbness. Rarely, allergic-type reactions have been reported during the clinical use of this product.

Symptoms/injuries after skin contact: None anticipated from normal handling of this product. However, inadvertent contact with this product may be irritating to broken skin and mucous membranes, and may produce numbness.

Symptoms/injuries after eye contact: Causes serious eye irritation. May produce numbness and blurred vision.

Symptoms/injuries after ingestion: Ingestion may cause numbness of the tongue and anesthetic effects on the stomach.

4.3. Indication of any immediate medical attention and special treatment needed

No additional information available

SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable extinguishing media: Use extinguishing media appropriate for surrounding fire.

Unsuitable extinguishing media: None.

5.2. Special hazards arising from the substance or mixture

Fire hazard: None known.

5.3. Advice for firefighters

Protection during firefighting: Do not enter fire area without proper protective equipment, including respiratory protection.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

General measures: No special measures required.

6.1.1. For non-emergency personnel
No additional information available

6.1.2. For emergency responders
No additional information available

6.2. Environmental precautions

Prevent entry to sewers and public waters.

6.3. Methods and material for containment and cleaning up

For containment: Stop the flow of material, if this is without risk.

Methods for cleaning up: Absorb any liquid with suitable material and clean affected area with soap and water. Dispose of spill materials according to the applicable federal, state, or local regulations.

6.4. Reference to other sections
No additional information available
SECTION 7: Handling and storage

7.1. Precautions for safe handling

Precautions for safe handling: No special handling required for hazard control under conditions of normal product use.

7.2. Conditions for safe storage, including any incompatibilities

Storage conditions: For product protection, follow storage recommendations noted on the product case label, the primary container label, or the product insert.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

(2S)-N-(2,6-Dimethylphenyl)-1-propylpiperidine-2-carboxamide (132112-35-7)

Not applicable

8.2. Exposure controls

Appropriate engineering controls: Local exhaust and general ventilation must be adequate to meet exposure standards.

Hand protection: If skin contact with the product formulation is likely, the use of latex or nitrile gloves is recommended.

Eye protection: Use protective goggles if eye contact is likely.

Skin and body protection: Wear suitable working clothes.

Respiratory protection: Respiratory protection is normally not needed during intended product use. However, if the generation of dusts or aerosols is likely, and engineering controls are not considered adequate to control potential airborne exposures, wear NIOSH approved respirator when handling.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state: Liquid
Appearance: Clear.
Color: Colorless
Odor: Odorless
Odor threshold: No data available
pH: 4.5 - 6 (1% solution)
Melting point: No data available
Freezing point: No data available
Boiling point: No data available
Flash point: No data available
Relative evaporation rate (butyl acetate=1): No data available
Flammability (solid, gas): No data available
Vapor pressure: No data available
Relative vapor density at 20 °C: No data available
Relative density: 1.002 - 1.005 (25°C)
Solubility: At 25°C ropivacaine HCl has a solubility of 53.8 mg/mL in water. It is freely soluble in methanol and soluble in isopropanol.

Log Pow: No data available
Auto-ignition temperature: No data available
Decomposition temperature: No data available
Viscosity, kinematic: No data available
Viscosity, dynamic: No data available
Explosion limits: No data available
Explosive properties: No data available
Oxidizing properties: No data available

9.2. Other information

No additional information available
SECTION 10: Stability and reactivity

10.1. Reactivity
No additional information available

10.2. Chemical stability
The product is stable at normal handling and storage conditions.

10.3. Possibility of hazardous reactions
Will not occur.

10.4. Conditions to avoid
Not determined.

10.5. Incompatible materials
Strongly alkaline conditions.

10.6. Hazardous decomposition products
During thermal decomposition, it may be possible to generate irritating vapors and/or toxic fumes of carbon oxides (COx), nitrogen oxides (NOx), and hydrogen chloride.

SECTION 11: Toxicological information

11.1. Information on toxicological effects

Acute toxicity : Not classified

Skin corrosion/irritation : Not classified. None anticipated from normal handling of this product. However, inadvertent contact with this product may be irritating to broken skin and mucous membranes, and may produce numbness.

Serious eye damage/irritation : Causes serious eye irritation.

Respiratory or skin sensitization : Not classified. None anticipated from normal handling of this product. However, inadvertent contact of this product with the respiratory system may produce irritation and numbness. Rarely, allergic-type reactions have been reported during the clinical use of this product.

Germ cell mutagenicity : Not classified. Weak mutagenic activity was seen in the mouse lymphoma test. Mutagenicity was not noted in other assays.

Carcinogenicity : Not classified. Long term studies in animals of most local anesthetics, including ropivacaine, to evaluate the carcinogenic potential have not been conducted.

Reproductive toxicity : Not classified. Studies conducted with ropivacaine in rats did not demonstrate an effect on fertility or general reproductive performance over 2 generations. Ropivacaine was administered subcutaneously to rabbits on gestation days 6-18 at dosages of 1.3, 4.2, or 13 mg/kg/day. Similarly, ropivacaine was given subcutaneously to rats on gestation days 6-15 at dosages of 5.3, 11 and 26 mg/kg/day. No teratogenic effects were observed in rats or rabbits at the highest dosages tested. In two pre-natal and post-natal studies, female rats were treated daily from day 15 of gestation to day 20 postpartum with subcutaneous dosages of 5.3, 11 and 26 mg/kg/day. There were no treatment-related effects on late fetal development, parturition, lactation, neonatal viability, or growth of the offspring. In another study, male rats were dosed daily for 9 weeks before mating and during mating. Females were dosed daily for 2 weeks before mating and then during the mating, pregnancy, and lactation, up to day 42 post coitus. At a dosage of 23 mg/kg/day, an increased loss of pups was observed during the first 3 days postpartum. The finding was considered secondary to impaired maternal care due to maternal toxicity.

Specific target organ toxicity (single exposure) : Not classified

Specific target organ toxicity (repeated exposure) : May cause damage to organs through prolonged or repeated exposure. Based on clinical use, possible target organs include the nervous system, cardiovascular system, and skin.

Aspiration hazard : Not classified

SECTION 12: Ecological information

12.1. Toxicity
Not determined for product. Information for ropivacaine hydrochloride is as follows:
*LC50(96 hr) = 38 mg/L in fish
*EC50(48 hr) = 34 mg/L in Daphnia magna
*EC50(72 hr) = 59 mg/L in green algae.
12.2. Persistence and degradability
Not readily biodegradable.

12.3. Bioaccumulative potential
No additional information available

12.4. Mobility in soil
No additional information available

12.5. Other adverse effects
Effect on the global warming: No known effects from this product.

SECTION 13: Disposal considerations

13.1. Waste treatment methods
Waste disposal recommendations: Dispose of contents/container in accordance with local/regional/national/international regulations.

SECTION 14: Transport information

Department of Transportation (DOT)
In accordance with DOT
Not applicable

SECTION 15: Regulatory information

15.1. US Federal regulations
No additional information available

15.2. US State regulations
No additional information available

SECTION 16: Other information

Full text of H-phrases:

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Eye Dam. 1</td>
<td>Serious eye damage/eye irritation Category 1</td>
</tr>
<tr>
<td>Eye Irrit. 2A</td>
<td>Serious eye damage/eye irritation Category 2A</td>
</tr>
<tr>
<td>STOT RE 2</td>
<td>Specific target organ toxicity (repeated exposure) Category 2</td>
</tr>
<tr>
<td>H318</td>
<td>Causes serious eye damage</td>
</tr>
<tr>
<td>H319</td>
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This information is based on our current knowledge and is intended to describe the product for the purposes of health, safety and environmental requirements only. It should not therefore be construed as guaranteeing any specific property of the product.